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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,820	10/05/2001	Dean A. Falb	7853-0248	2738
20583	7590	08/31/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			BURKHART, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/970,820

Applicant(s)

FALB ET AL.

Examiner

Michael D. Burkhardt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-74, 76-82 and 92-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-74, 76-82 and 92-98 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/5/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/4/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

Applicants Petition to accept a delayed priority claim, dated 4/4/05, has been granted. This application, filed 10/5/2001, is a CON of 09/176,330, filed 10/22/1998, abandoned 2/25/2002, which is a DIV of application 08/485,573, filed 6/7/1995, now U.S. Patent 5,968,770, which is a CIP of 08/386,844, filed 2/10/1995, now U.S. patent 6,156,500, issued 12/5/2000. The claimed invention recites antibodies specific for rchd523, which requires disclosure of the amino acid coding sequence. No coding sequence of rchd523 was disclosed in the 08/386,844 application, only a partial sequence of the 3' untranslated region. The full-length sequence of rchd523 was not disclosed until the 08/485,573 application. Hence, the invention is granted a priority date of 6/7/1995.

### ***Information Disclosure Statement***

The information disclosure statement filed 4/4/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Foreign patent and non-patent literature documents not submitted in this or a parent application have not been considered and crossed through.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76 has been amended to recite an antibody that immunospecifically binds to "one or more of the extracellular domains, or portions of the rchd523 amino acid sequence". Because the rchd523 protein consists of intracellular, extracellular, and transmembrane domains, it is unclear if the scope of the claim is limited to only those antibodies that bind to the extracellular domains, or those that bind the other "portions" of the rchd523 protein (i.e. the intracellular and transmembrane domains). Therefore, the metes and bounds of the claimed subject matter are unclear. This rejection affects all dependent claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-74, 76-82, and 92-98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

***Response to Arguments***

Applicant's arguments filed 4/4/05 have been fully considered but they are not persuasive. Applicants argue that: 1) the term "immunospecifically" has been interpreted too narrowly in light of the specification and that which is known in the art; 2) applicants provide references stating that a "specific" antibody may be cross-reactive with antigens that share an epitope; 3) the priority date of the instant application is before the date of Owman et al, cited in the enablement rejection; 4) the instant specification enables one of skill in the art to make and use the claimed antibody via disclosure of the amino acid and DNA sequences encoding rchd523; 5) the specification teaches use of the claimed antibody in the diagnosis of cardiovascular disease.

As detailed in the previous enablement rejection, there is no definition of "immunospecifically", and the immunology textbook passages submitted by applicants do not provide any further guidance for interpretation of the term. Nevertheless, these passages and applicants arguments underscore the point of the enablement rejection: that, lacking any specific working examples of the claimed antibody, most, if not all, antibodies or antisera raised to rchd523 would cross-react with CMKLR2. This is due to the complete conservation of the amino acid sequence of the two proteins except for a Q to R change at residue 138. Given that the disclosed use of the claimed antibody is detection of rchd523 in diagnostic assays (see claims 92-98, paragraphs [0184] and [0339] of the published application, and page 13 of applicants response dated 4/4/05), the claimed antibody must distinguish between these two proteins. Otherwise, how could one of skill in the art distinguish which protein, rchd523, CMKLR2, or both, was being detected in an assay? Therefore, the mere disclosure of the amino acid and

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corresponding DNA sequence of rchd523 does not enable one to make and use the claimed antibody commensurate in scope with the claims. The instant specification discloses no antibodies that might distinguish between rchd523 and CMKLR2, and does not provide any guidance on how to do so. Regarding the priority date of the application and publication date of Owman et al, this is not a prior art rejection, and there is no requirement that references in an enablement rejection be qualified as prior art.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

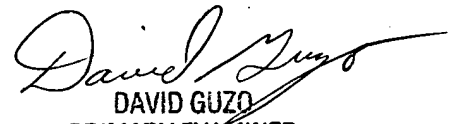
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart  
Examiner  
Art Unit 1633

  
DAVID GUZO  
PRIMARY EXAMINER